

### REMARKS

In this Preliminary Amendment and Response to Restriction and Election Requirements, Applicant has amended claims 1, 26, 28, 42, 57, and 65, and canceled claims 16 and 43. Applicant requests that these claim amendments be entered prior to substantive examination of this application. Claims 1-15, 17-42, and 44-68 will be pending in this application upon entry of these amendments.

#### Restriction and Election Requirements

Claims 1-68 have been restricted under 35 U.S.C. § 121 as follows:

- I. Claims 1-27, drawn to a method of monitoring a plurality of physiological parameters and physical activity levels indicative of sleep quality of delivering drug induced relaxation or sleep therapy,
- II. Claims 28-64, drawn to a medical system for monitoring a plurality of physiological parameters and physical activity levels indicative of sleep quality and delivering drug induced relaxation or sleep therapy, and
- III. Claims 65-68, drawn to computer-readable medium comprising instructions that cause a programmable processor to monitor a plurality of physiological parameters and physical activity levels indicative of sleep quality.

The claims were further restricted to first and second groupings of species. The Office Action indicates the first grouping of species is:

- A. "arousal" embodiment,
- B. "physical activity levels" embodiment,
- C. "melatonin" embodiment, and
- D. "sleep efficiency" embodiment.

The second grouping of species is:

- AA. "user-interface" embodiment,
- BB. "no user-interface" embodiment.

Applicant hereby provisionally elects Group I, including claims 1-27, with traverse. Applicant further provisionally elects Species B, relating to the "physical activity levels"

embodiment, without traverse.<sup>1</sup> Claims 1-6, 8, 9, 11, 16-33, 35, 36, 38, and 43-68 read on Species B. Applicant also provisionally elects Species BB without traverse. Claims 1-62 and 64-68 read on species BB. Thus, claims 1-6, 8, 9, 11 and 16-27 read on the combination of Group I, Species B, and Species BB.

Claims 1-15, 17-42, and 44-68 are pending after entry of the claim amendments. Consequently, according to Applicant's provisional election of Group I, Species B and Species BB, claims 1-15, 17-42 and 44-68 would be pending, with claims 1-6, 8, 9, 11 and 17-27 elected, and claims 28-42 and 44-68 withdrawn.

### ***Traversal***

Applicant hereby elects Group I with traverse. According to MPEP § 803, there are two criteria for a proper requirement for restriction between patentably distinct inventions: (A) The inventions must be independent (see MPEP §§ 802.01, 806.04, 808.01) or distinct as claimed (see MPEP §§ 806.05 - 806.05(i)); and (B) there must be a serious burden on the examiner if restriction is required (emphasis added).

### ***No Serious Burden***

Applicant believes that there is no serious burden on the Examiner with respect to examination of pending claims 1-15, 17-42, and 44-68 because many of the elements of the dependent claims are substantially similar. Although the independent claims of Groups I, II, and III differ in scope to the extent that the claims of Group I relate to a method, the claims of Group II relate to a medical system, and the claims of Group III relate to a computer-readable medium, the claims of Groups I, II, and III are each directed toward monitoring physiological parameters.

A serious burden is evidenced by a separate classification, status, or field of search. (See MPEP § 808.02). No such serious burden is presented by the examination of claims 1-64 of Groups I and II, because as indicated in the Office Action, claims 1-64 are classified in class 600, subclass 595. There is no serious burden in examining additional claims in the same classification.

---

<sup>1</sup> However, with respect to the Species elections, the Office Action indicated that no claims are generic. Applicant respectfully disagrees because independent claims 1, 28, 57, 62, and 65 are generic to Species A, B, C, and D, as well as to Species AA and BB.

Accordingly, Applicant requests withdrawal of the restriction requirement between Groups I, II, and III because examination of all pending claims 1-15, 17-42, and 44-68 does not present a serious burden on the Examiner.

***Process / Apparatus***

In the Office Action, the Examiner asserted that the claims of Groups I, II, and III are distinct from each other because Groups I and II are related as process and apparatus, and Groups I and III are related as process and apparatus. Applicant respectfully requests withdrawal of the requirement for restriction between Groups I, II, and III because the Examiner has not established that an apparatus of Group II or III as claimed can be used to practice a process that is materially different from that recited in the claims of Group I.

In support of the restriction between Groups I and II, and Groups I and III, the Examiner cites MPEP § 806.05(e), which states that inventions are distinct if it can be shown that either (A) the process as claimed can be practiced by another and materially different apparatus or by hand; or (B) that the apparatus as claimed can be used to practice another materially different process. The Examiner contends that the apparatus of Group II “can be used to practice another and materially different process such as periodically determining, monitoring, tracking, and displaying the three-dimensional spatial orientation of a patient via the plurality of orthogonally aligned accelerometers.” Similarly, the Examiner contends that the apparatus of Group III can be used to “periodically instruct a processor for determining, monitoring, and, [sic] tracking the three-dimensional spatial orientation of a patient.”

The “orthogonally aligned accelerometers” referred to by the Examiner with respect to Groups II and III are only recited in claim 31, which depends from independent claim 28. As a result, the Examiner has not provided an example of a materially different process in which the apparatus in any one of pending claims 28-30, 32-42, and 44-64 of Group II may be used. Furthermore the requirements of claim 31 of Group II and claim 4 of Group I are substantially similar in that they both require determining when a patient is recumbent based on signals from a plurality of orthogonally aligned accelerometers.

In view of the foregoing reasons, the Examiner has not established that the claims of Groups II or III can be used to practice a process that is materially different from that recited in the claims of Group I. The requirement for restriction between Groups I, II, and III should be withdrawn.

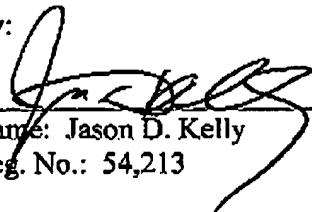
### CONCLUSION

All claims are in condition for allowance. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

6/30/06  
SHUMAKER & SIEFFERT, P.A.  
8425 Seasons Parkway, Suite 105  
St. Paul, Minnesota 55125  
Telephone: 651.735.1100  
Facsimile: 651.735.1102

By:

  
Name: Jason D. Kelly  
Reg. No.: 54,213